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The National Institutes of Health (NIH): Background and Congressional Issues

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Summary

The National Institutes of Health (NIH) is the focal point for federal health research. An agency of the Department of Health and Human Services (HHS), it uses its $30 billion budget to support more than 300,000 scientists and research personnel working at over 2,500 institutions across the United States and abroad, as well as to conduct biomedical and behavioral research and research training at its own facilities. The agency consists of the Office of the Director, in charge of overall policy and program coordination, and 27 institutes and centers, each of which focuses on particular diseases or research areas in human health. A range of basic and clinical research is funded through a highly competitive system of peer-reviewed grants and contracts.

The congressional authorization committees and appropriation committees face many issues in working with NIH to set research priorities in the face of tight budgets. The last time Congress addressed NIH with comprehensive legislation was in December 2006, when it passed the NIH Reform Act (P.L. 109-482). While the Public Health Service Act (PHSA) provides the statutory basis for NIH programs, it is primarily through appropriations report language, not budget line items or earmarks, that Congress gives direction to NIH and allows a voice for advocacy groups. Congress accepts, for the most part, the priorities established through the agency's complex process of weighing scientific opportunity and public health needs.

Congress doubled the NIH budget over a five-year period from its FY1998 base of $13.7 billion to the FY2003 level of $27.1 billion. Since then, the growth rate of the NIH budget has been below the rate of inflation, which for biomedical research in FY2015 is estimated to be 2.2%. An exception occurred when the American Recovery and Reinvestment Act (ARRA) of 2009 provided NIH with an additional $10.4 billion to be spent over the two-year period of FY2009 through FY2010.

The FY2013 appropriation provided an increase of almost $70 million for the NIH Office of the Director, but it also required an across-the-board rescission of 0.2% for all accounts. In addition, a March 1, 2013, sequestration order and a transfer of funding under the authority of the HHS Secretary further reduced FY2013 amounts for NIH by $1.553 billion and $173 million, respectively, leaving the agency with an FY2013 program level budget of $29.151 billion. The Consolidated Appropriations Act, 2014 (P.L. 113-76), provided an NIH program level total of $30.151 billion, a $1 billion increase over the FY2013 post-sequester level. The NIH program level in FY2015 is $30.311 billion. The President's FY2016 budget requests an NIH program level total of $31.311 billion, an increase of $1 billion (3.3%) over the FY2015 level.

Challenges facing the agency and the research enterprise, all aggravated by restrained budgets, include attracting and keeping young scientists in research careers; improving the translation of research results into useful medical interventions through more efficient clinical research; creating opportunities for transdisciplinary research that cuts across institute boundaries to exploit the newest scientific discoveries; and managing the portfolio of extramural and intramural research with strategic planning, openness, and public accountability.

Also of concern is the position of U.S. biomedical research compared with the investments being made by other countries. A January 2015 study found that the total U.S. (public and private) share of global biomedical research funding declined from 57% in 2004 to 44% in 2012 while Asia, particularly China, tripled its investment from $2.6 billion (2004) to $9.7 billion (2012). Globally, the United States continues to be the top supporter of both public and industry medical research.

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Introduction

The National Institutes of Health (NIH) is the primary agency of the federal government charged with performing and supporting biomedical and behavioral research. It also has major roles in training biomedical researchers and disseminating health information. The NIH mission is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."[1]

Congress maintains a high level of interest in NIH for a variety of reasons. NIH funds extramural researchers in every state, and widespread constituencies contact Congress about funding for particular diseases and levels of research support in general. NIH is the largest and most visible contributor to the federal biomedical research effort; it represents about half of federal spending for non-Department of Defense research and development (R&D) and about one-fifth of total federal R&D funding. In both budget (about $30 billion) and personnel (about 18,000 people), it is the largest of the eight health-related agencies that make up the Public Health Service (PHS) within the Department of Health and Human Services (HHS) and constitutes more than one-third of all HHS discretionary spending.[2] The agency garners great interest during deliberations on the annual appropriations bill for the Departments of Labor, Health and Human Services, and Education and Related Agencies.

NIH increasingly comes to the attention of Congress and the American people due to greater awareness of science advances. Examples include the Human Genome Project and its potential for guiding more personalized medicine, and the possibility of research advances improving the quality and lowering costs of medical care. Although Congress doubled the NIH budget between FY1998 and FY2003 and provided a temporary two-year funding increase through the American Recovery and Reinvestment Act of 2009 (P.L. 111-5) recent appropriations have provided the agency with low or no growth in the post-doubling period.

The FY2013 appropriation provided an increase of almost $70 million for the NIH Office of the Director; however, it also required an across-the-board rescission of 0.2% for all accounts.[3] In addition, a March 1, 2013, sequestration order and a transfer of funding under the authority of the HHS Secretary further reduced FY2013 amounts for NIH by $1.553 billion and $173 million, respectively, leaving the agency with an FY2013 program level budget of $29.151 billion. The Consolidated Appropriations Act, 2014 (P.L. 113-76), provided an NIH program level total of $30.150 billion, a $1 billion increase over the FY2013 post-sequester level. The NIH program level in FY2015 is $30.311 billion. The President's FY2016 budget requests an NIH program level total of $31.311 billion, an increase of $1 billion (3.3%) over the FY2015 level.

Aside from funding, other issues of concern to Congress and the research community include

- increasing the movement of basic science discoveries, via translational research, into new preventives, diagnostics, therapies, and cures;
- helping young investigators obtain their first independent research grants;

[1] National Institutes of Health, About the National Institutes of Health, at http://www.nih.gov/about/mission.htm.

[2] The Public Health Service also includes the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Indian Health Service (IHS), and the Agency for Toxic Substances and Disease Registry (ATSDR). For further information, see CRS Report R43304, *Public Health Service Agencies: Overview and Funding*, coordinated by C. Stephen Redhead.

[3] Pursuant to Section 3004, as interpreted by the Office of Management and Budget. Consolidated and Further Continuing Appropriations Act, 2013 (P.L. 113-6).

- congressional restrictions on research funding, such as work involving human embryos or human sexuality.

This report provides background and analysis on NIH organization, mission, budget, and history; outlines the agency's major responsibilities; and discusses some of the issues facing Congress as it works to guide and monitor the nation's investment in medical research.

Background on NIH

History

NIH traces its roots to 1887, when a one-room Laboratory of Hygiene was established at the Marine Hospital in Staten Island, NY. Relocated to Washington, DC, in 1891, and renamed the Hygienic Laboratory, it operated for its first half century as an intramural research lab for the Public Health Service. Congress designated the research laboratory the National Institute of Health in 1930 (P.L. 71-251). It moved to donated land in the Maryland suburbs in 1938. By 1948, several new institutes and divisions had been created, and the agency became the National Institutes of Health (P.L. 80-655). Congress has continued to create new institutes and centers, most recently in 2011 with the establishment of the National Center for Advancing Translational Sciences (NCATS, P.L. 112-74). NIH occupies a 322-acre main campus in Bethesda, MD, and several off-campus sites, including locations in Maryland, North Carolina, Montana, Arizona, and elsewhere.

Organizational Structure

Today, NIH consists of the Office of the Director and 27 components—20 research institutes, 3 research centers, the National Library of Medicine (NLM), and 3 other centers that provide operational support to the rest of NIH (for details, see **Table 1**). The Office of the Director (OD) sets overall policy for NIH and coordinates the programs and activities of all NIH components, particularly trans-institute research initiatives and issues. The individual institutes and centers (ICs), each of which focuses on particular diseases, areas of human health and development, or aspects of research support, plan and manage their own research programs in coordination with OD. Congress provides separate appropriations to 24 (all 20 institutes, NLM, and the 3 research centers) of the 27 ICs, to OD, and to a buildings and facilities account (see "Budget").[4] The institutes, NLM and the three research centers have the

Selected NIH Resources
http://www.nih.gov

Background: http://www.nih.gov/about/index.html

Budget: http://officeofbudget.od.nih.gov/index.htm

Research, condition & disease funding estimates: http://report.nih.gov/categorical_spending.aspx

Health Information: http://health.nih.gov

Office of the Director, Institutes & Centers: http://www.nih.gov/icd

Grants & grants policy: http://grants1.nih.gov/grants/oer.htm

Grants searchable by topic: http://projectreporter.nih.gov/reporter.cfm

Grants searchable by recipient, location, etc.: http://report.nih.gov/index.aspx

Peer review: http://grants.nih.gov/grants/peer_review_process.htm

Chronologies (historical & legislative): http://www.nih.gov/about/almanac/index.html

Congressional Liaison: 301-496-3471, http://olpa.od.nih.gov

[4] The three centers that do not receive their own appropriations are the Center for Scientific Review (CSR), which receives, refers, and reviews research and training grant applications; the Center for Information Technology (CIT), which coordinates NIH information technology services; and the Clinical Center (CC), NIH's hospital and outpatient

authority to award research grants; the three operational support centers do not award research grants.

NIH's massive organizational structure has been an issue of concern.[5] The costs and complexities of administering the agency have multiplied as new entities were created, each with its own mission, budget, staff, review office, and other organizational apparatus. The resulting fragmentation might adversely impact NIH's ability to respond appropriately to new scientific and public health challenges. In response, Congress requested that the National Academy of Sciences (NAS) study the structure and organization of NIH. The NAS report was released in 2003: *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*.[6]

The 2003 NAS report found that "the most common mechanism of origin of the institutes has been the congressional mandate responding to the health advocacy community."[7] The first institute to be established was the National Cancer Institute (NCI) in 1937. "From the middle 1940s to 1974, health advocates were successful in persuading Congress to establish additional institutes, often against the wishes of administrations, which generally opposed creation of new categorical institutes."[8] Health advocacy "groups have continued the long established pattern of pushing for creation of named entities at NIH to create focal points for developing more research funding for particular diseases. That has often resulted in the establishment by Congress of a named program at the office level. Through continued pressure, offices may then be elevated to centers and, in some cases, to institute status."[9] The 2003 NAS report suggested potential mergers, but said that any proposals for changing the number of ICs or OD program offices should be subject to a public evaluation process.[10]

Many of the recommendations in the 2003 NAS report were incorporated into the NIH Reform Act of 2006 (P.L. 109-482).[11] The law enhanced the authority of the NIH Director's Office to perform strategic planning, provided for trans-NIH initiatives by enacting the Common Fund into law and required strategic planning for the Fund. It established the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director and moved a number of individual program offices (coordinating research on AIDS, women's health, behavioral and social sciences, and disease prevention) in OD to DPCPSI. The law established

facility for clinical research. Funding is through the NIH Management Fund, which is financed by taps on other NIH appropriations. For further information, see the *NIH Almanac* at http://www.nih.gov/about/almanac/about.htm.

[5] Harold Varmus, "Proliferation of National Institutes of Health," *Science*, vol. 291 (March 9, 2001), pp. 1903-1905.

[6] National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* (Washington: National Academies Press, 2003), http://www.nap.edu/catalog/10779.html. Congress requested this study from NAS in 2000. U.S. Congress, Senate Committee on Appropriations, *Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Bill, 2001*, Report to Accompany S. 2553, 106th Cong., 2nd sess., May 21, 2000, S.Rept. 106-293, p. 179.

[7] National Research Council and Institute of Medicine, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges*, p. 36.

[8] Ibid., p. 46.

[9] Ibid.

[10] Ibid., p. 7. The NAS report recommended more rigorous and frequent review of the performance of top NIH and IC leaders, including the possibility of term limits; reassessment by Congress of the National Cancer Institute's special status regarding appointments and budget authority; and reform of the advisory council system so that it is more independent and protected from political influences.

[11] A detailed summary of the provisions of the NIH Reform Act may be found on the website of the NIH Office of Legislative Policy and Analysis (OLPA), at http://olpa.od.nih.gov/legislation/109/publiclaws/reformact06.asp. See the OLPA website for its Bill Tracking pages and other links to congressional activity, at http://olpa.od.nih.gov/tracking/.

the Council of Councils to advise the NIH Director on the policies and activities of DPCPSI and to participate in developing proposals for trans-NIH research.[12] The law requires a biennial report from the Director to Congress assessing the state of biomedical research and reporting in detail on the research activities of NIH, including strategic planning and initiatives, and summaries of research in a number of broad areas.[13]

The Reform Act required the creation of a comprehensive electronic reporting system to catalogue research activities from all of the ICs in a standardized format. Information from the tracking system assists the Director and DPCPSI in planning trans-NIH research initiatives that cannot be handled within individual ICs. The reporting system, called Research Portfolio Online Reporting Tools (RePORT), "provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH-supported research."[14]

The Reform Act did not contain any provisions on specific diseases or fields of research, nor did it eliminate or consolidate any existing ICs. However, it did provide certain authorities to HHS and NIH officials for making organizational changes to NIH and created the Scientific Management Review Board (SMRB) to provide advice on the use of those organizational authorities.[15] SMRB is charged with formally and publicly reviewing NIH organizational structure at least once every seven years. SMRB may recommend restructuring but the number of ICs is capped at the current 27. The law set out time frames for the Director to take action on such recommendations, and provided for review by Congress.

Authority

NIH derives its statutory authority from the Public Health Service Act of 1944, as amended (42 U.S.C. §§201-300mm-61). Section 301 of the PHS Act (42 U.S.C. §241) grants the Secretary of HHS broad permanent authority to conduct and sponsor research. In addition, Title IV, "National Research Institutes" (42 U.S.C. §§281-290b), authorizes in greater detail various activities, functions, and responsibilities of the NIH Director and the institutes and centers. All of the institutes and centers are covered by specific provisions in the PHS Act, but they vary considerably in the amount of detail included in the statutory language.

The last major NIH reauthorization was the NIH Reform Act of 2006 (P.L. 109-482). Prior to its passage, nine of the ICs and a variety of individual programs had time-and-dollar limits on their authorizations of appropriations. Most of the authorizations had expired, but annual appropriations acts together with Section 301 provided authority for the programs. The other institutes and centers and most NIH programs did not require periodic reauthorization by Congress, and there was no overall authorization of appropriations for the agency. The NIH Reform Act authorized total funding levels for NIH appropriations for FY2007 through FY2009, and eliminated all of the other specific authorizations of appropriations in Title IV. Since 2006, a

[12] The Council is composed of representatives from the IC advisory councils, OD offices, and the Council of Public Representatives.

[13] See http://report.nih.gov/biennialreport/. All other duplicative reporting requirements were eliminated. The law added new reporting requirements on clinical trials, human tissue storing and tracking, whistleblower complaints, and special consultant hires (all had been the subject of investigations by the House Energy and Commerce Committee).

[14] The home page for RePORT is at http://report.nih.gov/index.aspx. It includes links to a number of compiled tables, charts, and data sets, as well as sites for performing tailored searches on funded awards and other topics of interest. See http://projectreporter.nih.gov/reporter.cfm for grant searches and http://report.nih.gov/rcdc/categories/ for "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)."

[15] See http://smrb.od.nih.gov/index.asp.

few specific authorizations have been added to Title IV; overall authorization expired at the end of FY2009 and has not been extended by Congress.

NIH Research Activities

Two categories of research are sponsored by the institutes and centers: *extramural research*, performed by non-federal scientists using NIH grant or contract money, and *intramural research*, performed by NIH scientists in the NIH laboratories and Clinical Center. In both the extramural and intramural programs, the research projects are largely investigator-initiated, and span all fields of basic and clinical medical and behavioral research. (Basic research is research in the fundamental medical sciences, sometimes called lab or bench research, while clinical research involves patients.) NIH also supports a range of extramural and intramural *research training programs* to prepare young investigators for research careers, and engages in a number of *information dissemination* activities to reach various audiences.

Extramural Research

The extramural research community includes more than 300,000 scientists and research personnel affiliated with over 2,500 universities, academic health centers, hospitals, and independent research institutions.[16] More than 80% of the overall NIH budget is spent on extramural awards in the form of research grants, research and development contracts, training awards, and a few smaller categories. Within the large "research grants" category, the bulk of the funding goes for research project grants (RPGs) awarded to individual investigators and small teams. Other types of grants are provided to groups of researchers who work in collaborative programs or in multidisciplinary centers that focus on particular diseases or areas of research. Data on awards and recipients by state, by congressional district, by type of institution, and by subject of the research may be accessed from the NIH website.[17]

Peer Review

Scientists who wish to compete for NIH extramural research funding, whether for totally new proposals or for renewal of previous grant awards, submit detailed applications that describe the research they plan to undertake. NIH considers the applications under a two-tiered system of peer review. First, the applications are reviewed for scientific and technical merit by committees called "study sections" composed of 12 to 22 nongovernment scientists who are experts in the relevant fields of research.[18] Most applications for research project grants are investigator-initiated; they are assigned for review to one of the 170 study sections administered by the Center for Scientific Review (CSR).[19] Some applications are submitted in response to solicitations by ICs for research areas the ICs wish to target and for which they have set aside funding. These solicitations are known as RFAs (for grants, Requests for Applications) and RFPs (for contracts, Requests for Proposals).[20] Applications responding to RFAs and RFPs are reviewed by study sections within the ICs.

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[16] U.S. Department of Health and Human Services, *FY2016 Budget in Brief*, p. 45, http://www.hhs.gov/budget/fy2016/fy-2016-budget-in-brief.pdf.

[17] See the NIH Research Portfolio Online Reporting Tools (RePORT) at http://report.nih.gov/index.aspx.

[18] Jeffrey Mervis, "Peering into peer review," *Science*, vol. 343 (February 7, 2014), pp. 596-598.

[19] Ibid., p. 597.

[20] An umbrella term is "Funding Opportunity Announcement" (FOA), which is defined as follows in the "Glossary of

Three times a year, members of study sections convene to read, discuss, and score the most recent batch of submitted research proposals, on average about 70 applications per year.[21] Each application that appears strong enough upon first reading to have a chance of receiving funding is thoroughly discussed and given a "priority score" that represents the average of the scores assigned by the reviewers. That score becomes the main determinant in whether an applicant will eventually receive funding from an IC for the research proposal. For the most part, applications are funded in the order of their priority score percentile until the IC has committed all of its available resources. In 2013, "more than 24,000 scientists reviewed roughly 75,000 applications at some 2500 panel meetings. CSR's budget to manage the entire operation was $110 million."[22]

The funding decisions, however, are fine-tuned by a second level of peer review in the ICs, when the applications are considered for program relevance by the National Advisory Councils or Boards of the ICs. Advisory Councils and Boards are composed of scientific and lay representatives. These groups sometimes recommend funding certain applications that fall just outside the normal cutoff if the research is of a type that an IC is particularly interested in promoting. IC staff make the final funding decisions among the top priority proposals.[23]

Awards

A successful grant applicant receives an award that will be funded for several years. The average length of a research project grant award is just under four years; hence, in any given year, about three-fourths of the grantees are in "noncompeting," or "continuation," status. Each year, a noncompeting grantee has to submit a project report to the IC that supplied the funding, but the grantee does not have to compete for the second, third, and fourth year of funding—the IC considers the award a budgetary commitment. At the expiration of the award, the grantee may choose to compete for a renewal of the project. In FY2014, in addition to making over 9,100 new and competing renewal awards, NIH made more than 23,000 noncompeting awards and over 1,600 small business awards, for a total of over 34,000 RPGs.[24] The average annual cost of an RPG award was about $489,000 in FY2014, including both direct and indirect costs.[25] The direct costs, averaging 72.5% of the total award in FY2014, cover project-specific expenses, while the indirect costs, averaging 27.5%, pay for facility and administration costs (i.e., overhead) of the institution where the research is conducted.[26]

NIH Terms" (http://grants.nih.gov/grants/glossary.htm): "A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program. Funding opportunity announcements can be found at Grants.gov/FIND and in the NIH Guide for Grants and Contracts."

[21] Mervis, "Peering into peer review," p. 597.

[22] Ibid.

[23] Further information on NIH peer review policies can be found at http://grants.nih.gov/grants/peer/peer.htm.

[24] NIH, *FY2016 Justification of Estimates for Appropriations Committees, Vol. I, Overview*, "Budget Mechanism Table," p. 25, http://officeofbudget.od.nih.gov/br.html.

[25] NIH, *FY2016 Justification, Vol. I, Overview*, table on "Research Project Grants: Total Number of Awards and Dollars," p. 98, http://officeofbudget.od.nih.gov/br.html.

[26] NIH, *FY2016 Justification, Vol. I, Overview*, table on "Statistical Data—Direct and Indirect Costs Awarded," p. 97, http://officeofbudget.od.nih.gov/br.html.

Intramural Research

The NIH intramural research program (IRP), at about $3.5 billion, accounts for approximately 11% of the budget.[27] It includes about 5,300 scientists and technical support staff who are government employees, and another 5,000 young scientists at various stages of research training who come to NIH for a few years to work as non-employee trainees, including about 3,800 postdoctoral fellows.[28] Other IRP personnel include administrative support staff, guest researchers, and contractors.

Almost all of the ICs have an intramural research program, but the size, structure, and activities of the programs vary greatly.[29] Many intramural scientists work in the Clinical Center, which houses both basic research laboratories and clinics for scientists involved with patient care in clinical research studies. This arrangement facilitates interdisciplinary collaboration and the direct clinical application of new knowledge derived from basic research. Periodic reviews of IC intramural research programs are conducted by each IC's Board of Scientific Counselors, composed of external experts.

Research Training

Research training to prepare students and young scientists for research careers is supported through both the extramural and intramural research programs. Pre-doctoral and postdoctoral training opportunities are available for both basic and clinical scientists through a variety of training grants, fellowships, and loan repayment programs. The largest extramural program is called the Ruth L. Kirschstein National Research Service Awards (NRSA) program, authorized by Section 487 of the PHS Act. Programs offered on the NIH campus range from summer internships for high school students to five-year fellowships for postdoctoral scientists.

Information Dissemination

NIH has important roles in translating the knowledge gained from biomedical research into medical practice and useful health information for the general public. The individual institutes and centers carry out many relevant activities, such as sponsoring seminars, meetings, and consensus development conferences to inform health professionals of new findings; answering thousands of telephone, mail, and online inquiries; publishing physician and patient education materials on the Internet and in print; supporting information clearinghouses and running public information campaigns on various diseases; and making specialized databases available.[30]

Budget

At about $30 billion for FY2015, NIH's budget constitutes a considerable portion—more than one-third—of all HHS discretionary spending, and is much larger than those of other PHS

[27] U.S. Department of Health and Human Services, *FY2016 Budget in Brief*, p. 49, http://www.hhs.gov/budget/fy2016/fy-2016-budget-in-brief.pdf.

[28] Personal communication with the NIH Office of Intramural Research, January 4, 2013.

[29] See links to individual IC programs at http://irp.nih.gov/our-research/our-programs/text. ICs that do not have an intramural research component are the National Institute of General Medical Sciences (NIGMS), the Fogarty International Center (FIC), and the Center for Scientific Review (CSR).

[30] Free searching of MEDLINE citations and other NLM databases, together with resources for health questions, is available at http://medlineplus.gov and at http://health.nih.gov.

agencies such as FDA ($2.6 billion), CDC ($6.1 billion), HRSA ($6.1 billion), Indian Health Service ($4.6 billion) and SAMHSA ($3.5 billion).[31] It also represents about 40% of federal spending for non-Department of Defense research and development (R&D) and about 20% of total federal R&D funding.[32]

Congress doubled the NIH budget in five years, from a base of $13.65 billion in FY1998 to $27.1 billion in FY2003. Annual increases in the 14%-15% range were the norm during the five-year doubling period. In contrast, over the post-doubling period increases from regular appropriations have been between 1.0% and 3.2% each year.[33] The growth rate of the NIH budget has been at or below the rate of inflation, which for biomedical research in FY2015 is estimated to be 2.2%.[34] Since FY2003—the peak of the doubling period—in constant 2012 dollars, NIH funding in FY2015 is 22% lower than the FY2003 level.[35]

Sources of Funding

Funding for NIH comes primarily from the annual Labor-HHS-Education (Labor-HHS) appropriations act, which funds the agency through 26 separate accounts. An additional small amount for environmental research and training related to Superfund comes from the Interior, Environment, and Related Agencies (Interior-Environment) appropriations act. Those two sources constitute NIH's discretionary budget authority.

The NIH "program level" budget takes into account other funds that are added to or transferred from the agency.[36] At present, NIH receives: (1) mandatory funds (currently $150 million a year) for type 1 diabetes research under PHS Act §330B; and, (2) funds from a "program evaluation" transfer authorized by Section 241 of the PHS Act (42 U.S.C. §238j). The mandatory diabetes funds are appropriated in separate legislation, most recently by P.L. 112-240 in FY2014 and P.L. 113-93 in FY2015, and are proposed for reauthorization in the FY2016 budget request. Language extending the diabetes funds through 2017 is included in Section 213 of H.R. 2 which passed the House on March 26, 2015.

From FY2003 through FY2014, NIH received an extra $8.2 million annually for the National Library of Medicine (NLM) from a transfer within PHS called the Program Evaluation Set-Aside. NIH and other PHS agencies within HHS are subject to this budget "tap" which has been used to

[31] U.S. Department of Health and Human Services, *Fiscal Year 2016 Budget in Brief*, p. 16, http://www.hhs.gov/budget/fy2016/fy-2016-budget-in-brief.pdf.

[32] See CRS Report R43580, *Federal Research and Development Funding: FY2015*, coordinated by John F. Sargent Jr.

[33] For further information, see CRS Report R43341, *NIH Funding: FY1994-FY2016*, by Judith A. Johnson.

[34] The Biomedical Research and Development Price Index (BRDPI) is developed each year for NIH by the Bureau of Economic Analysis of the Department of Commerce. It reflects the increase in prices of the resources needed to conduct biomedical research—including personnel services, supplies, equipment—and indicates how much the NIH budget must change to maintain purchasing power. See http://officeofbudget.od.nih.gov/gbiPriceIndexes.html.

[35] For further information, see CRS Report R43341, *NIH Funding: FY1994-FY2016*, by Judith A. Johnson.

[36] For a number of years, part of the NIH annual appropriation was transferred to the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria. In FY2002-FY2007, about $100 million of the annual appropriation to NIAID was transferred to the Global Fund (the FY2004 amount was $149 million). For FY2008, the amount was increased to $300 million in the request, and the final amount of the transfer from the NIH/NIAID appropriation was $295 million. For FY2009 and FY2010, $300 million of the NIH/NIAID appropriation was transferred to the Global Fund, and $297 million in FY2011. The "NIH program level" cited in agency and OMB budget documents, however, did not reflect the Global Fund transfer. Congress decided to terminate the Global Fund transfer from NIH in the FY2012 Consolidated Appropriations Act and instead provided all funding for the Global Fund through the Department of State/Foreign Operations appropriations.

fund not only program evaluation activities, but also functions that are seen as having benefits across PHS, such as NLM, the National Center for Health Statistics in CDC and the entire discretionary budget of the Agency for Healthcare Research and Quality.[37] These and other uses of the evaluation tap by the appropriators have the effect of redistributing appropriated funds among PHS agencies.

Although the PHS Act limits the tap to no more than 1% of eligible appropriations, in recent years the annual Labor, HHS, and Education appropriations act has specified a higher amount (2.5% in FY2015) and also typically directs specific amounts of funding from the tap for transfer to a number of HHS programs. NIH, with the largest budget among the PHS agencies, is the largest "donor" of program evaluation funds ($689 million in FY2015), and had been, until recently, a relatively minor recipient.[38] However, P.L. 113-235, the Consolidated and Further Continuing Appropriations Act, 2015, provided NIH with $715 million in FY2015 from the PHS Act transfer, allocating the entire amount to the National Institute of General Medical Sciences (NIGMS). This transfer offset the more than $700 million reduction in discretionary budget authority for NIGMS in the law compared with its FY2014 funding level. The President's FY2016 budget request proposes $847 million in funding transferred to NIH via the PHS Program Evaluation Set-Aside.

Budget Formulation

The NIH budget request that Congress receives from the President each February for the next fiscal year reflects both recent history and professional judgments about the future, because it needs to support both ongoing research commitments and new initiatives. The request is formulated through a lengthy process that starts more than a year before in the institutes and centers. The budget then evolves over a number of months as it moves from the ICs to NIH, then to HHS and finally to the Office of Management and Budget (OMB). At each stage, IC and NIH needs are weighed in the context of the larger budget. Eventually, Congress is called upon to make similar judgments.

As a continuing process, IC leaders, with input from the scientific community, define the most important and promising areas in their respective fields. They consider whether the research portfolio they are already supporting needs any rebalancing, and they decide on possible new initiatives for the coming budget year. An annual budget retreat in May brings together the IC leaders with top NIH management to discuss policies and priorities under various budget scenarios. They might consider, for example, what the different emphases in their programs would be if the appropriation turned out to be a certain percent decrease, a flat budget, or an increase. The presentations and discussions allow NIH management to develop the budget request they will submit to HHS, taking into account the estimate of the amount of funding needed to support the "commitment base" of continuing awards, the funding desired for unsolicited new research proposals, the new initiatives that the Director wants to incorporate, and guidance from the department about the request (for example, there might be an instruction to pay no inflation increases on grants).

At the HHS level, NIH's request is considered in the context of the overall department budget, resulting in a notice back to NIH on the department's allowance. There are usually appeals and adjustments made before the final HHS budget goes to OMB. The process of submission,

[37] For further information on the Program Evaluation tap, see CRS Report R43304, *Public Health Service Agencies: Overview and Funding*, coordinated by C. Stephen Redhead.

[38] U.S. Department of Health and Human Services, "Use of Public Health Service Set-Aside Authority for Fiscal Year 2015, Report to Congress." Includes a table at the end of the report that lists the amount of set-aside funds donated and received by each agency and office in FY2015.

passback, and appeals is repeated as OMB considers the entire federal budget and tells HHS what amounts and policy approaches are approved for incorporation into the President's final budget that will be sent to Congress. Once the budget is made public all agency comments about the request are expected to support the President's proposed levels.

NIH Budget by Funding Mechanism

A common way to describe the NIH budget is by "funding mechanism," meaning grants, contracts, training, research centers, etc., as shown in **Figure 1**. Displaying budget data by mechanism reveals the balance between extramural and intramural funding, as well as the relative emphasis on support of individual investigator-initiated research versus funding of larger projects.

Given that since FY2003 the NIH budget has lost 22% of its purchasing power, the agency's two major concerns are maintaining support of investigator-initiated research through research project grants, and continuing to sustain the pipeline of new investigators.[39] Total FY2016 funding for RPGs at $17.206 billion represents about 55% of NIH's budget. The FY2016 request would support an estimated 35,447 awards; within that total, 10,303 would be competing RPGs and the average annual cost of a competing RPG for FY2016 would be about $461,000.[40] (Competing awards are new grants plus competing renewals of existing grants.) The expected "success rate" of applications receiving funding would be 19.3% for FY2016 compared with 21% for FY2010.[41] The success rate was 30% in FY2003.[42] The decrease in purchasing power—22% lower than in FY2003—has caused a tightening of the ability on NIH to support new projects, and therefore a decline in the proportion of grant applicants who are successful at getting funded. Estimated success rates for the various ICs in FY2016 range from lows of 9.4% for the Common Fund and 10.3% for the National Center for Complementary and Integrative Health (NCCIH) to highs of 45.2% for the Fogarty International Center (FIC) and 39.7% for awards made by the Office of Research Infrastructure Programs (ORIP) and the Science Education Partnership Awards (SEPA).[43]

[39] See, for example, the testimony of NIH Director Francis S. Collins, "Driving Innovation through Federal Investments," appearing before the Senate Appropriations Committee, hearing, April 29, 2014, http://www.nih.gov/about/director/congressionalhearings/04292014drivinginnovation.htm.

[40] NIH, *FY2016 Justification, Vol. I, Overview*, table on "Research Project Grants: Success Rates," p. 98, http://officeofbudget.od.nih.gov/br.html.

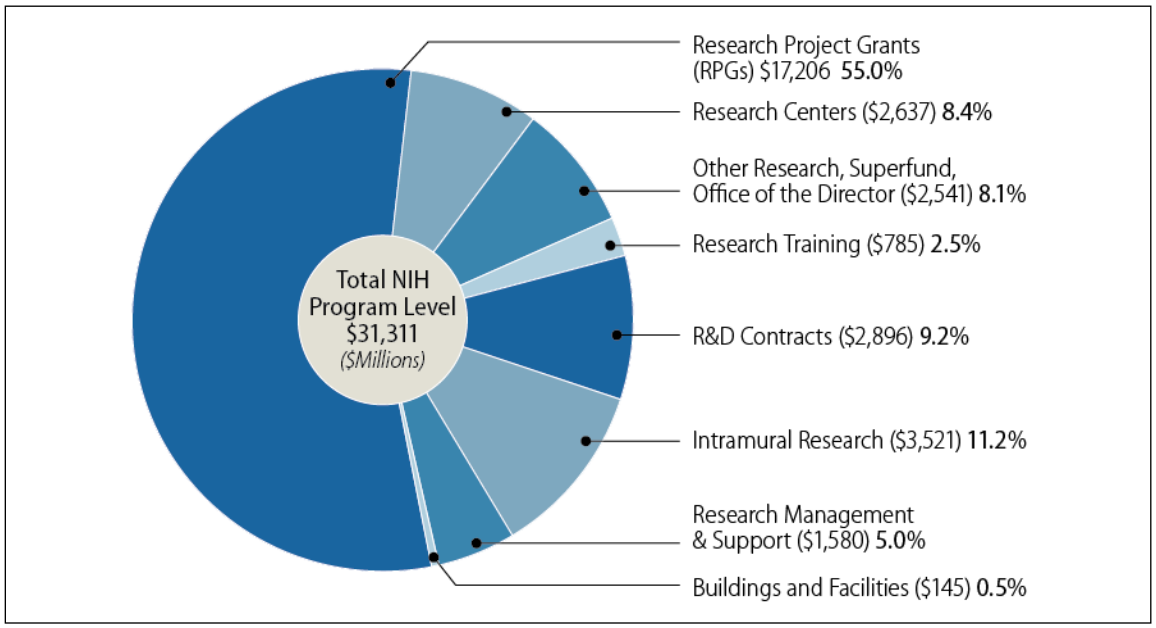
[41] Application success rates represent the percentage of applications that are awarded during the fiscal year. NIH provides statistics on the "success rate" of research project grant (RPG) applications—the number of competing RPG applications funded *divided by* the number of applications reviewed. NIH, *FY2016 Justification, Vol. I, Overview*, table on "Research Project Grants: Success Rates," p. 99, http://officeofbudget.od.nih.gov/br.html.

[42] NIH, *Justification of Estimates for Appropriations Committees, FY2012, Vol. I, Overview*, table on "Research Project Grants: Success Rates, FY2003-FY2012," p. OA-47, at http://officeofbudget.od.nih.gov/pdfs/FY12/Tab%202%20Overall%20Appropriations.pdf.

[43] NIH, *FY2016 Justification, Vol. I, Overview*, table on "Research Project Grants: Success Rates," p. 99, http://officeofbudget.od.nih.gov/br.html. For more information on ORIP, see http://dpcpsi.nih.gov/orip/index. For more information on SEPA, see http://dpcpsi.nih.gov/orip/ose/sepa/office_of_science_education.

Figure 1. FY2016 NIH Budget Request by Funding Mechanism

Dollars in Millions



Source: Adapted from U.S. Department of Health and Human Services, *FY2016 Budget in Brief*, p. 49, http://www.hhs.gov/budget/fy2016/fy-2016-budget-in-brief.pdf.

Setting NIH Research Priorities

Congress has increasingly scrutinized how NIH has used its resources, how it can most efficiently adapt to budgetary constraints, and how its 27 semi-autonomous institutes and centers can best coordinate their efforts in order to identify and respond to important public health challenges.

Congressional Involvement in NIH Research Priorities

Appropriators have traditionally avoided specifying dollar amounts for particular fields of research or mechanisms of funding aside from the level of the Institute and Center accounts. For example, the joint explanatory statement that accompanies the Consolidated Appropriations Act, 2014 (P.L. 113-76) stated the following: "In accordance with longstanding tradition, funding is not directed to any specific disease research area. The NIH is expected to base its funding decisions only on scientific opportunities and the peer review process."[44] However, appropriators may use report language directing NIH to focus research on particular diseases. In the following example, the FY2014 joint explanatory statement rejects a proposal made by the Obama Administration to set a specific funding level for Alzheimer's disease research but encourages NIH to spend a significant portion of the recommended increase in funding for the National Institute on Aging (NIA) on such research:

> The fiscal year 2014 budget request calls for a $80,000,000 increase over the fiscal year 2012 funding level for Alzheimer's disease research at NIA. In keeping with longstanding practice, the House and Senate Appropriations Committees do not recommend a specific

[44] U.S. Congress, Consolidated Appropriations Act, 2014, (P.L. 113-760, H.R. 3547 Joint Explanatory Statement, Division H, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2014.

> amount of NIH funding for this purpose or for any other individual disease. Doing so would establish a dangerous precedent that could politicize the NIH peer review system. Nevertheless, in recognition that Alzheimer's disease poses a serious threat to the Nation's long-term health and economic stability, the agreement expects that a significant portion of the recommended increase for NIA should be directed to research on Alzheimer's. The exact amount should be determined by the scientific opportunity of additional research on this disease and the quality of grant applications that are submitted for Alzheimer's relative to those submitted for other diseases.[45]

Some bills may encourage or instruct NIH to conduct research in particular areas, but funding for specific research areas generally remains subject to the overall discretionary appropriation level and the NIH peer review process. However, the explanatory statement on P.L. 113-235, the Consolidated and Further Continuing Appropriations Act, 2015, states that the law provides an increase of over $25 million to NIA, and, without specifying an amount, encourages NIH to direct a significant portion of the increase for research on Alzheimer's disease. In addition, the law specifies that $12.6 million is added to the Common Fund for the purpose of carrying out pediatric research as authorized in the Gabriella Miller Kids First Research Act (P.L. 113-94). The Common Fund is part of OD and is intended to support research in emerging areas of scientific opportunity, public health challenges, or knowledge gaps that might benefit from collaboration between two or more institutes or centers.

Research Restrictions

From time to time, the research community has been unsettled by congressional attempts to cancel funding for specific existing peer-reviewed grants.[46] The targeted studies have tended to be in fields of behavioral research, including some in mental health and human sexuality research. Sponsors and supporters of such amendments to the L-HHS-ED appropriations bills say that NIH should not be devoting scarce resources to research studies whose value they question. Researchers, however, including NIH leadership, have expressed alarm at what they view as an assault on the peer review system, saying that such studies were funded because of their technical merit and the important research questions they addressed.[47] Perhaps the most prominent example is controls on federal funding of research on human embryonic stem cells. Although President Barack Obama signed an executive order in March 2009 that reversed the nearly eight-year-old George W. Bush Administration restriction on federal funding for human embryonic stem cell research, funding for some aspects of such research is still limited by a provision in the annual Labor-HHS-ED appropriations act—the so-called Dickey amendment.[48]

Cures Acceleration Network

Health reform legislation enacted in March 2010 (P.L. 111-148, the Patient Protection and Affordable Care Act, ACA) amends the PHS Act (Section 402C) requiring the NIH Director to implement the Cures Acceleration Network (CAN). The purpose of CAN is to support revolutionary advances in basic research and facilitate FDA review of CAN-funded cures. ACA authorized $500 million for CAN in FY2010 and such sums as necessary for subsequent fiscal years. CAN is to be funded via a specific appropriation and cannot be funded using the general

[45] Ibid.

[46] Jocelyn Kaiser, "House 'Peer Review' Kills Two NIH Grants," *Science*, vol. 309 (July 1, 2005), pp. 29-31.

[47] Ibid.

[48] For further information, see CRS Report RL33540, *Stem Cell Research: Science, Federal Research Funding, and Regulatory Oversight*, by Judith A. Johnson and Edward C. Liu.

NIH appropriation. The CAN appropriation was $9.9 million in FY2012, $9.4 million in FY2013, $9.8 million in FY2014, and $9.8 million in FY2015; the request for FY2016 is $25.8 million.

CAN authorizing language states that the NIH Director determines which medical products (drugs, devices, biological products, or combination products) are "high need cures," based upon (1) their ability to diagnose, prevent, or treat harm from a disease or condition; and (2) the lack of market incentives for their adequate or timely development. NIH then makes awards to public or private research entities, medical centers, biotechnology or pharmaceutical companies, and patient advocacy groups in order to accelerate the development of such high need cures.[49] A CAN Review Board advises the Director on the activities of CAN and on significant barriers to the translation of basic science into clinical applications. The CAN Review Board submits reports to HHS regarding any barrier identified. The Director is required to respond to such recommendations in writing. Although advocacy groups, such as the Parkinson's Action Network and the Council for American Medical Innovation, have voiced strong support for the creation of CAN, others have concerns about providing federal funds to industry without sufficient accountability to ensure that the taxpayer receives a return on the investment.[50]

NIH Process in Setting Research Priorities

NIH weighs numerous factors when it makes research priority-setting decisions. In addition to advice from Congress and the Administration, NIH seeks input from the scientific community, NIH staff, patient organizations, voluntary health associations, the Advisory Councils for each NIH Institute and Center, and the Advisory Committee to the NIH Director.[51] Two other entities also provide NIH with advice and guidance: the NIH Director's Council on Public Representatives and the Scientific Management Review Board.[52] Judgments about public health needs are most important; this may reflect, for example, information on the health and/or economic burdens posed by particular diseases, the populations affected, and the degree of threat to the general public.[53] Another factor may be the potential applicability of research on one medical condition to broader, related fields. The process of formulating the NIH budget provides a framework within which research priorities are identified, reviewed, and justified. Each NIH

[49] ACA specified three different CAN awards. The *Cures Acceleration Partnership Awards* provide up to $15 million for the first year with a matching requirement; eligible entities must provide non-federal matching funds of $1 for every $3 funded by CAN. *The Cures Acceleration Grant Awards* are similar but have no matching requirement. The *Cures Acceleration Flexible Research Awards* would be available if the Director determined that the goals of CAN could not be met otherwise, and would consist of awards not to exceed 20% of the total funds appropriated for CAN.

[50] Alyah Khan, "Proposal to Expedite Product Development Makes Senate Health Bill," *Inside Health Policy—Inside Health Reform*, January 6, 2010.

[51] The 2003 NAS report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges* recommended that the NIH advisory councils become more involved in priority setting and planning.

[52] The NIH Director's Council of Public Representatives (COPR) was established in 1998 following the release of the Institute of Medicine report, "Scientific Opportunities and Public Needs," which urged the establishment of COPR "to facilitate interactions between NIH and the general public." The Scientific Management Review Board was authorized by the NIH Reform Act of 2006 (P.L. 109-482) which provides certain organizational authorities to HHS and NIH officials regarding the NIH institutes and centers and the Office of the Director. The Scientific Management Review Board advises HHS and NIH officials on the use of these organizational authorities.

[53] For example, in response to a November 5, 2014, Obama Administration request, $238,000,000 was provided in P.L. 113-235 to the National Institute for Allergy and Infectious Diseases (NIAID) for research on Ebola. For more information, see CRS Report R43807, *FY2015 Funding to Counter Ebola and the Islamic State (IS)*, coordinated by Susan B. Epstein.

Institute determines how to allocate its funds among the many different research areas within its broadly defined mission.

The 2003 NAS report, *Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges,* recommended that Congress strengthen the role of the NIH Director in strategic planning and budgeting for innovative, trans-NIH research. The NIH Reform Act of 2006 (P.L. 109-482) enhanced the authority of the NIH Director's Office to perform strategic planning, especially facilitating and funding trans-disciplinary, cross-institute research initiatives.

The Reform Act also created a special office, the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). It "identifies important areas of emerging scientific opportunity or rising public health challenges to assist in the acceleration of research investments in these areas."[54] The Office of Strategic Coordination within DPCPSI manages the NIH Common Fund which supports large complex research efforts that involve the collaboration of two or more research institutes or centers. The Office of Strategic Coordination works with staff and leadership across NIH to identify and promote NIH-wide scientific opportunities that receive Common Fund support.[55]

Balancing New and Existing Budget Commitments

Spending caps in congressional budget resolutions have left the Labor-HHS-ED appropriations subcommittees with difficult choices when allocating funds for a range of social and public health programs. The NIH budget shifted from annual increases of around 6% to 7% before FY1999, to twice that (around 14% to 15%) during the doubling period, to levels at or below the rate of inflation (between 0% and 3%) since FY2003, with a brief respite in FY2009 and FY2010 due to ARRA funds.

The FY1998 to FY2003 appropriations resulted in an increase in the number of new grants funded and the average dollar size of grants as well as an overall expansion of research facility construction. NIH appropriations since FY2003 have consistently been at or below the rate of inflation and have strained certain areas of the biomedical research enterprise, particularly investigator-initiated research.

Coping with the reality of budget constraints may require NIH and the research community to rethink the traditional approach to the way biomedical research is funded in the United States. For example, one observer notes that because of funding constraints and the accompanying lower success at obtaining grant funds, "biomedical researchers are spending far too much effort writing grant applications and reviewing those of others, leaving precious little time to do what they should be doing: reading the scientific literature and thinking deeply about their research and teaching."[56] He goes on to say that this situation is due to "reliance on the NIH to pay not only the salaries of scientists but also the overhead (or indirect costs) of building and construction and maintenance.… [This] "perverse incentive encourages U.S. universities, medical centers, and other research institutions to expand their research capacities indefinitely through funds derived from NIH research grants."[57] One possible solution may be "for NIH to require that at least half

[54] See http://www.nih.gov/about/researchplanning.htm.

[55] See http://dpcpsi.nih.gov/osc/.

[56] Bruce Alberts, "Overbuilding Research Capacity," *Science*, vol. 329 (September 10, 2010).

[57] Ibid.

of the salary of each principal investigator be paid by his or her institution, phasing in this requirement gradually over the next decade."[58]

NIH Director Francis Collins alluded to this problem in a January 2010 interview, stating that universities are "becoming too reliant on NIH money, allowing faculty members to obtain all their income from federal research grants."[59] Dr. Collins indicated that when faculty members run multiple research projects at the same time, "that turns that investigator into a grant-writing machine perhaps more than a doing-of-science machine."[60] However, he said, any new restrictions on NIH grants "would have to be phased in over a fairly long period of time because many universities and faculty members would find that quite disruptive."[61]

NIH Initiatives to Assist Young Investigators

NIH is concerned that prospects for a lower number of grants and a lower success rate will further discourage young scientists from pursuing careers in medical research.[62] New investigators with creative ideas are the lifeblood of the research enterprise, but the path to becoming an independent researcher is long and challenging. Many young doctoral students and postdoctoral scientists already observe that their more senior colleagues have had increasing trouble in getting funded. Especially if they are physicians with the option of going into clinical practice, they may wonder about the wisdom of devoting themselves to years of research training that may not lead to successful competition for independent grant support. Some may decide on other career paths, and some may choose to pursue research opportunities overseas.

Over the years, NIH has created a series of initiatives to assist new researchers in obtaining independent funding. Despite these efforts, the average age at which a new investigator first obtains an independent grant increased from 36 years for PhDs or 38 years for MDs in 1980 to 42 years for PhDs or 45 years for MDs in 2013.[63] In addition, the success rate for new investigators fell from 40% in 1962 to 27% in 2013.[64] On the other hand, some might argue that special efforts to retain new investigators in academia is unnecessary, that the problem may be driven by the doubling of the NIH budget, and that the correct number of new investigators is unknown.

Recent efforts undertaken by NIH to assist young investigators include introduction of the Pathway to Independence in 2006, the NIH Director's New Innovator Award in 2007, and Early Stage Investigators in 2009.[65] The Pathway to Independence program supports promising postdoctoral scientists through five-year awards that have a two-year mentored phase and a three-year independent phase.[66] The NIH Director's New Innovator Award aims to support highly innovative research that has been proposed by promising new investigators.[67] The program

[58] Ibid.

[59] Paul Basken, "NIH Will Give Less and Demand More in 2010, New Leader Says," *The Chronicle of Higher Education*, January 17, 2010.

[60] Ibid.

[61] Ibid.

[62] See, for example, the testimony of NIH Director Francis S. Collins, "Driving Innovation through Federal Investments," appearing before the Senate Appropriations Committee, hearing, April 29, 2014, http://www.nih.gov/about/director/congressionalhearings/04292014drivinginnovation.htm.

[63] See New Investigator Data 1980 - 2013 at http://grants2.nih.gov/grants/new_investigators/index.htm#data.

[64] Ibid.

[65] See http://grants2.nih.gov/grants/new_investigators/index.htm.

[66] See http://grants2.nih.gov/grants/new_investigators/index.htm#indaward.

[67] See http://grants2.nih.gov/grants/new_investigators/index.htm#award, and http://commonfund.nih.gov/newinnovator/

supports a small group of unusually creative new investigators with innovative research ideas at a stage in their career when they may not necessarily have the preliminary data required to fare well in the traditional NIH peer review system.

One change made to the peer review system was a new policy of clustering the review of research applications submitted by Early Stage Investigators "with the expectation that they will be evaluated more effectively when judged against applications from scientists at the same stage of their careers."[68] Early Stage Investigators are defined as "a New Investigator who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet been awarded a substantial, competing NIH research grant."[69]

Balancing Federal and Industry Support of Research vs. Global Investment

NIH basic research is valued as a source of new and improved treatment and prevention measures but may also be used as a basis for policy decisions, economic development, and potentially new commercial products. The primary rationale for a federal government role in funding basic research is that private firms do not perform enough such research relative to the needs of society.[70] Private firms may lack the incentive to adequately support basic research because firms cannot ensure that they will capture all the benefits of such support.[71] There is some concern that, given the size of federal research funding, without careful decision making, some of the federal funding could possibly "crowd out private-sector investment in R&D."[72] The federal government tends to focus on basic research and private firms concentrate on applied research and development, which may lower the risk of overlap or crowd out. However, the line between basic and applied research can be difficult to define. This is especially true when basic life-science research may be profitable.

Federal support of basic research not only *directly* stimulates industry spending on applied research and development (R&D) through scientific discoveries that expand industry R&D opportunities but also *indirectly* stimulates industry R&D by training many of the researchers that are hired by industry.[73] The training provided by NIH programs "enhances the productivity and profitability of the companies' R&D investments."[74] In contrast, NIH funding may indirectly affect the number of researchers available for the private sector; this can indirectly affect the salaries of these researchers.

One recent study, published in January 2015, found that in 2012 industry accounted for 58% of all U.S. expenditures on biomedical research, followed by NIH (27%), state and local governments (5%), and private not-for-profit support (4%).[75] This study also compared investment in

index.

[68] National Institutes of Health, "New NIH Policy Establishes Goals to Support Scientists Early in Their Careers," press release, October 31, 2008, http://www.nih.gov/news/health/oct2008/od-31.htm.

[69] See http://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm.

[70] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, Washington, DC, October 2006, p. 3.

[71] Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, Washington, DC, February 1993, p. 201.

[72] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, Washington, DC, October 2006, p. 3.

[73] Ibid.

[74] Ibid.

[75] Hamilton Moses, David H. M. Matheson, Sarah Cairns-Smith, et al., "The Anatomy of Medical Research: U.S. and

biomedical research in the United States and in other developed countries. It found that "U.S. government research funding declined from 57% (2004) to 50% (2012) of the global total, as did that of U.S. companies (50% to 41%), with the total U.S. (public plus private) share of global research funding declining from 57% to 44%. Asia, particularly China, tripled investment from $2.6 billion (2004) to $9.7 billion (2012) preferentially for education and personnel."[76] Globally, the United States continues to be the top supporter of both public and industry medical research.

Although there continues to be frequent calls for increased support for biomedical research, some recognize that this is unlikely to occur—given the current federal fiscal constraints and the risk-averse nature of industry investment in research—and propose that completely new sources of funding are required.[77] The January 2015 study agrees with this assessment and provides the following observation:

> New investment is required if the clinical value of past scientific discoveries and opportunities to improve care are to be fully realized. Sources could include repatriation of foreign capital, new innovation bonds, administrative savings, patent pools, and public-private risk sharing collaborations. Given international trends, the United States will relinquish its historical international lead in the next decade unless such measures are undertaken.[78]

Some Members of Congress have expressed concern over the investments being made by other countries in biomedical research. In Section 809, "Policy Statement on Medical Discovery, Development, Delivery and Innovation," H.Con.Res. 27 found that the "United States leadership role is being threatened, however, as other countries contribute more to basic research from both public and private sources" ... and that the "Organisation for Economic Development and Cooperation [sic] predicts that China, for example, will outspend the United States in total research and development by the end of the decade."

Another analysis of U.S. biomedical research, published in April 2014, concluded that "the current system contains systemic flaws that are threatening its future."[79] The authors of this study observed that "even the most successful scientists and most promising trainees are increasingly pessimistic about the future of their chosen career. Based on extensive observations and discussions, we believe that these concerns are justified and that the biomedical research enterprise in the United States is on an unsustainable path."[80] In the authors opinion, the "root cause of the widespread malaise is a longstanding assumption that the biomedical research system in the United States will expand indefinitely at a substantial rate. We are now faced with the stark realization that this is not the case. Over the last decade, the expansion has stalled and even reversed."[81]

International Comparisons," *Journal of the American Medical Association*, vol. 313, no. 2 (January 13, 2015), pp. 174-189.

[76] Ibid.

[77] Jose-Maria Fernandez, Roger M. Stein, and Andrew W. Lo, "Commercializing biomedical research through securitization techniques," *Nature Biotechnology*, vol. 30, no. 10 (October 2012), pp. 964-975.

[78] Hamilton Moses, David H. M. Matheson, Sarah Cairns-Smith, et al., "The Anatomy of Medical Research: U.S. and International Comparisons," *Journal of the American Medical Association*, vol. 313, no. 2 (January 13, 2015), p. 174.

[79] Bruce Alberts, Marc W. Kirschner, Shirley Tilghman, and Harold Varmus, "Rescuing U.S. biomedical research from its systemic flaws," *Proceedings of the National Academy of Sciences*, vol. 111, no. 16 (April 22, 2014), pp. 5773-5777.

[80] Ibid., p. 5773.

[81] Ibid.

The April 2014 analysis provides several recommendations for change to the biomedical research enterprise including: predictable and stable budgets for science funding agencies; multiple changes to biomedical training and workforce development programs; and, an improved peer review system. The authors also recommend a grant mechanism approach used by the Howard Hughes Medical Institute which involves selecting and providing stable support for successful scientists, "focusing as much (or more) on the overall quality of their science as on their proposed projects.... This approach is under active discussion among NIH leadership."[82]

On the other hand, perhaps enough is being spent, or has been spent, on biomedical research. Some have argued that because health care costs have been rising faster than GDP, and that about half the increase is from technology—namely advances in biomedical science funded for the most part by NIH—perhaps the agency, industry, and policy makers need to take a careful look at altering this vicious cycle:

> The NIH conducts and funds research that develops new insights; those insights spawn new expensive clinical interventions that drive up the cost of health care; and the increasing cost of care raises Medicare and Medicaid expenditures, which increases the federal budgets and deficits, which in turn threatens biomedical research funding.[83]

The pharmaceutical industry claims it must charge high prices for new therapies because the cost of drug discovery is high, estimated at $1.3 billion to $1.6 billion.[84] Others have criticized these estimates, claiming they are "false and built on seriously flawed methods, including debatable accounting theory and premised on blind faith in the confidential information supplied by the drug industry to its economic consultants at two universities who were paid by the same industry to do the job. The true cost is likely to be below $100 million."[85] One recent estimate states that the "median costs were a third less than the average, or $60 million. Deconstructing other inflators would lower the estimate of costs even further."[86]

Although the pharmaceutical industry frequently uses the word "innovative" when referring to new drugs, in fact, of the drugs approved for marketing each year by the FDA, only a portion (approximately 20% to 30%) are really innovative, meaning newly discovered or synthesized molecules, what the FDA calls new molecular entities (NMEs).[87] "And of the NMEs, only a fraction are developed entirely by the drug companies themselves. Most of the rest are simply licensed or otherwise acquired from university or government laboratories or biotechnology companies."[88]

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[82] Ibid., p. 5776.

[83] Ezekiel J. Emanuel, "The future of biomedical research," *JAMA*, vol. 309, no. 15 (April 17, 2013), pp. 1589-1590.

[84] Stephen Whitehead, "Making medicines evergreen," (rapid response), *BMJ*, December 17, 2012.

[85] Peter C. Gotzsche, "Making medicines evergreen," (rapid response), *BMJ*, December 17, 2012. See also: Arnold S. Relman and Marcia Angell, "America's other drug problem: how the drug industry distorts medicine and politics," *The New Republic*, December 16, 2002, pp. 27-41; Marcia Angell, "How much does the pharmaceutical industry *really* spend on R&D?," in *The truth about the drug companies: How they deceive us and what to do about it* (New York: Random House, 2004), pp. 37-41; Merrill Goozner, *The $800 million pill: The truth behind the cost of new drugs* (Berkeley: University of California Press, 2005); and, Donald W. Light, "Misleading Congress about Drug Development," *Journal of Health Politics, Policy and Law*, vol. 32, no. 5 (October 2007), pp. 895-913.

[86] Donald W. Light and Joel R. Lexchin, "Pharmaceutical research and development: what do we get for all that money?," *BMJ*, August 7, 2012.

[87] FDA, Summary of NDA Approvals and Receipts, 1938 to the Present, http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SummaryofNDAApprovalsReceipts1938tothepresent/default.htm

[88] Marcia Angell, "How much does the pharmaceutical industry *really* spend on R&D?," p. 43.

Increased time to develop a new drug, such as longer clinical trial times, have been cited as one factor causing high drug prices. However, a study published in 2006 of "clinical trial and regulatory review periods for drugs approved between 1992 and 2002" found that "clinical trial periods have not increased during this time frame and regulatory review periods have decreased. Therefore, it is unlikely that longer clinical trial times are contributing to rising prescription drug prices."[89] In addition, government support during drug development does not seem to translate into cost savings. A study published in 2005 found that "despite significant government support and rapid development times, HIV and cancer drugs are among the most highly priced medications in the United States."[90] The authors of this 2005 state that their "results suggest that higher HIV and cancer drug prices cannot be justified on the basis of longer development times and therefore drugs are more likely to be priced based on other factors such as patient and provider demand or other market factors." According to a former CEO of Merck, Raymond V. Gilmartin, "The price of medicines isn't determined by their research costs. Instead, it is determined by their value in preventing and treating disease. Whether Merck spends $500 million or $1 billion developing a medicine, it is the doctor, the patient, and those paying for our medicines who will determine its true value."[91]

The value of many new therapies has been called into question as well. For example, the anticancer agent Avastin (bevacizumab) "has not been shown to cure any patient. At best, this drug prolongs life a median of 3 to 5.3 months in metastatic colon cancer and 2 months in non-small-cell lung cancer. The cost is approximately $5,000 per month of treatment, and the cost-effectiveness ratio is approximately $140,000 per quality-adjusted life year for colorectal cancer and exceeds $500,000 for lung cancer."[92]

Perhaps a greater emphasis needs to be placed on "developing biomedical technologies that are not just 'incredibly exciting' but also cost lowering and value enhancing. ... Focusing research on cost-lowering, quality improving interventions has not been an NIH priority. This change in focus is vital to the future of both the country and the NIH."[93]

The challenge for Congress is to balance the continued funding for biomedical research to enhance longevity and quality of life—through public funding of the NIH and other agencies and encouragement of industry R&D—against the concurrent objectives of lowering costs and ensuring the quality and benefit of health care interventions.

[89] Salommeh Keyhani, Marie Diener-West, and Neil Powe, "Are development times for pharmaceuticals increasing or decreasing?," *Health Affairs*, vol. 25, no. 2 (March/April 2006), pp. 461-468.

[90] Salomeh Keyhani, Marie Diener-West, and Neil Powe, "Do drug prices reflect development time and government investment?," *Medical Care*, vol. 43, no. 8 (August 2005), pp. 753-762.

[91] Arnold S. Relman and Marcia Angell, "America's other drug problem: how the drug industry distorts medicine and politics," *The New Republic*, December 16, 2002, p. 32.

[92] Ezekiel J. Emanuel, "The future of biomedical research," *JAMA*, vol. 309, no. 15 (April 17, 2013), pp. 1589-1590.

[93] Ibid.

Table 1. Components of NIH, with History and Scope

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus
National Cancer Institute (NCI) PHSA §410-417D, 42 U.S.C. §285-285a-10	1937—National Cancer Institute Act (P.L. 75-244). 1944—under the PHS Act of 1944 (P.L. 78-410), NCI became a division of the National Institute of Health.	All aspects of cancer—cause, diagnosis, prevention, treatment, rehabilitation, and continuing care of patients.
National Heart, Lung, and Blood Institute (NHLBI) PHSA §415-425, 42 U.S.C. §285b-285b-8	1948—National Heart Act (P.L. 80-655): National Heart Institute. 1969—National Heart and Lung Institute. 1976—NHLBI.	Diseases of the heart, blood vessels, lungs, and blood; sleep disorders; and blood resources management.
National Institute of Dental and Craniofacial Research (NIDCR) PHSA §453, 42 U.S.C. §285h	1948—National Dental Research Act (P.L. 80-755): National Institute of Dental Research. 1998—NIDCR.	Oral, dental, and craniofacial diseases and disorders.
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) PHSA §426-434A, 42 U.S.C. §285c-285c-9	1950—Omnibus Medical Research Act (P.L. 81-692): National Institute of Arthritis and Metabolic Diseases. 1972—National Institute of Arthritis, Metabolism, and Digestive Diseases. 1981—National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1985—NIDDK.	Diabetes, endocrinology, metabolic diseases; digestive diseases, nutrition; kidney, urologic, hematologic diseases.
National Institute of Neurological Disorders and Stroke (NINDS) PHSA §457-460, 42 U.S.C. §285j-285j-3	1950—Omnibus Medical Research Act (P.L. 81-692): National Institute of Neurological Diseases and Blindness. 1968—National Institute of Neurological Diseases and Stroke. 1975—National Institute of Neurological and Communicative Disorders and Stroke. 1988—NINDS.	Convulsive, neuromuscular, demyelinating, and dementing disorders; fundamental neurosciences; stroke, trauma.
National Institute of Allergy and Infectious Diseases (NIAID) PHSA §446-447B, 42 U.S.C. §285f-285f-3	1955—established under authority of Omnibus Medical Research Act (P.L. 81-692).	Allergic, immunologic, and infectious diseases.

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus
National Institute of General Medical Sciences (NIGMS) PHSA §461, 42 U.S.C. §285k	1962—PHS Act Amendment (P.L. 87-838) authorized the Surgeon General to establish an institute for general (basic) biomedical sciences. 1963—NIGMS created in the Department of Health, Education, and Welfare (HEW).	Research and research training in basic biomedical sciences (cellular and molecular biology, genetics, pharmacology, physiology). Special focus on minority researchers and institutional capacity building.
National Institute of Child Health and Human Development (NICHD) PHSA §448-452G, 42 U.S.C. §285g-285g-10	1962—PHS Act Amendment (P.L. 87-838) authorized the Surgeon General to establish an institute for research on child health and human development. 1963—NICHD created in HEW.	Reproductive biology; population issues; embryonic development; maternal, child, and family health; medical rehabilitation.
National Eye Institute (NEI) PHSA §455-456, 42 U.S.C. §285i-285i-1	1968—National Eye Institute Establishment Act (P.L. 90-489) (functions were formerly in the institute covering neurological diseases and blindness).	Eye diseases, visual disorders, visual function, preservation of sight, health problems of the visually impaired.
National Institute of Environmental Health Sciences (NIEHS) PHSA §463-463A, 42 U.S.C. §285*l*-285*l*-1	1969—The NIH Division of Environmental Health Sciences (established by the Surgeon General in 1965) was elevated to institute status by the Secretary of HEW.	Interrelationships of environmental factors, individual genetic susceptibility, and age as they affect health. NIEHS is located in Research Triangle Park, NC.
National Institute on Aging (NIA) PHSA §443-445J, 42 U.S.C. §285e-285e-11	1974—Research on Aging Act of 1974 (P.L. 93-296).	Biomedical, social, and behavioral research on the aging process; diseases, problems, and needs of the aged.
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) PHSA §435-442A, 42 U.S.C. §285d-285d-8	1986—Established under authority of the Health Research Extension Act of 1985 (P.L. 99-158). For earlier history, see NIDDK.	Arthritis; bone, joint, connective tissue and muscle disorders; skin diseases.
National Institute on Deafness and Other Communication Disorders (NIDCD) PHSA §464-464F, 42 U.S.C. §285m-285m-6	1988—National Deafness and Other Communication Disorders Act of 1988 (P.L. 100-553) (functions were formerly in the institute covering neurological and communicative disorders and stroke).	Disorders of hearing, balance, smell, taste, voice, speech, and language.

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus
National Institute of Nursing Research (NINR) PHSA §464V-464Y, 42 U.S.C. §285q-285q-3	1986—National Center for Nursing Research established under authority of the Health Research Extension Act of 1985 (P.L. 99-158). 1993—NINR.	Acute and chronic illness, health promotion/disease prevention, nursing systems, clinical therapeutics.
National Institute on Alcohol Abuse and Alcoholism (NIAAA) PHSA §464H-464J, 42 U.S.C. §285n-285n-2	1970—Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act (P.L. 91-616) established NIAAA within NIMH in PHS. 1974—moved to Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) (P.L. 93-282). 1992—moved to NIH (P.L. 102-321).	Causes of alcoholism, how alcohol damages the body, prevention and treatment strategies.
National Institute on Drug Abuse (NIDA) PHSA §464L-464P, 42 U.S.C. §285o-285o-4	1974—established under authority of Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255). 1974—moved to ADAMHA (P.L. 93-282). 1992—moved to NIH (P.L. 102-321).	Social, biological, behavioral, and neuro-scientific bases of drug abuse and addiction; causes, prevention, and treatment strategies.
National Institute of Mental Health (NIMH) PHSA §464R-464U, 42 U.S.C. §285p-285p-3	1949—established under authority of National Mental Health Act of 1946 (P.L. 79-487). 1967—transferred out of NIH to PHS (P.L. 90-31). 1974—moved to ADAMHA (P.L. 93-282). 1992—moved back to NIH (P.L. 102-321).	Brain research, mental illness, and mental health.
National Human Genome Research Institute (NHGRI) PHSA §464z-1, 42 U.S.C. §285s	1989—National Center for Human Genome Research (NCHGR) established. 1993—NCHGR authorized (P.L. 103-43). 1997—designated an institute by the HHS Secretary. 2007—name officially changed in the PHS Act from NCHGR to NHGRI (P.L. 109-482).	Chromosome mapping, DNA sequencing, database development, ethical/legal/social implications of genetics research.
National Institute of Biomedical Imaging and Bioengineering (NIBIB) PHSA §464z, 42 U.S.C. §285r	2000—NIBIB Establishment Act (P.L. 106-580).	Research, training and coordination in biomedical imaging, bioengineering and related technologies and modalities, including biomaterials and informatics.

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus
National Institute on Minority Health and Health Disparities (NIMHD) PHSA §464z-3-464z-6, 42 U.S.C. §285t-285t-3	1990—Office of Research on Minority Health (ORMH) created by NIH in OD. 1993—ORMH authorized (P.L. 103-43). 2000—National Center on Minority Health and Health Disparities (NCMHD) created (P.L. 106-525). 2010—NCMHD redesignated as NIMHD (P.L. 111-148).	Research, training, and coordination on minority health conditions and populations with health disparities.
National Center for Complementary and Integrative Health (NCCIH) PHSA §485D, 42 U.S.C. §287c-21	1992—Office of Alternative Medicine (OAM) created in OD. 1993—OAM authorized (P.L. 103-43). 1999—National Center for Complementary and Alternative Medicine (NCCAM) created (P.L. 105-277). 2014—name changed from NCCAM to National Center for Complementary and Integrative Health (P.L. 113-235).	Identifies, evaluates, and researches unconventional health care practices.
John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) PHSA §482, 42 U.S.C. §287b	1968—established by HEW. 1985—established in law (P.L. 99-158).	Focal point for NIH's international collaboration activities and scientific exchanges; provides leadership in global health.
National Center for Advancing Translational Sciences (NCATS)[a] PHSA §479-480, 42 U.S.C. §287-287a	2011—NCATS established (P.L. 112-74).	Research to improve the processes for translating laboratory-based scientific discoveries into new drugs, diagnostics, and medical devices for patients.
National Library of Medicine (NLM) PHSA §465-478A, 42 U.S.C. §286-286d	1836—established as the Library of the Office of the Surgeon General of the Army, later Army Medical Library (1922), Armed Forces Medical Library (1952), and NLM under PHS (1956, NLM Act, P.L. 84-941). 1968—moved to NIH.	Collects, organizes, and makes available biomedical information; sponsors programs to improve U.S. medical library services.
Office of the Director (OD) PHSA §402, 42 U.S.C. §282	1930—Ransdell Act (P.L. 71-251) created the National Institute of Health.	Overall NIH leadership, planning, and coordination; liaison with HHS. Includes program offices overseeing research on AIDS, women's health, behavioral and social sciences, disease prevention, and research infrastructure support.
Buildings and Facilities (B&F) PHSA §402(b), 42 U.S.C. §282(b)	First separate appropriation FY1970.	Provides for the design, construction, improvement, and repair of NIH clinical and laboratory buildings.

Institute/Center Statutory Authority in Public Health Service Act and *U.S. Code*	When and How Established; Chronology of Name Changes	Major Research Focus
NIH Clinical Center (CC)	1944—authorized by the PHS Act (P.L. 78-410). 1953—first patient admitted.	NIH's hospital and outpatient facility for clinical research.
Center for Scientific Review (CSR)	1946—Division of Research Grants created. 1997—reorganized and renamed CSR.	Receives, assigns, and reviews research and training grant applications.
Center for Information Technology (CIT)	1964—Division of Computer Research and Technology (DCRT) established. 1998—CIT formed (DCRT combined with other offices).	Provides, coordinates, and manages information technology for NIH; research to advance computational science.

Sources: *NIH Almanac,* http://www.nih.gov/about/almanac/index.html.

a. The former National Center for Research Resources (NCRR) was dissolved on December 23, 2011, by the law that created the National Center for Advancing Translational Sciences (P.L. 112-74, Division F, §221). NCRR programs were transferred to NCATS, various other NIH institutes, and OD. NCRR authority was formerly found in PHSA §479-481D (42 U.S.C. §287-287a-4). History: 1970—Division of Research Resources (DRR) moved to NIH from PHS. 1990—NCRR created by merging DRR and Division of Research Services (statutory authority in NIH Revitalization Act of 1993, P.L. 103-43). Major programs focused on extramural and intramural research resources and technologies: clinical research resources and training, biomedical technology including computing, instrument systems, animal resources and facilities, nonmammalian research models, research infrastructure and capacity building.

Author Information

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